## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: NAKAJIMA=7

In re Application of:
 Hiroshi NAKAJIMA et al

Art Unit: Not Assigned

Art Unit: Not Assigned

Examiner: Not Assigned

Washington, D.C.

For: PSYCHOTROPIC AGENT
ANALGESIC AGENT...

Atty. Docket: NAKAJIMA=7

Conf. No.: Not Assigned

Washington, D.C.

June 14, 2006

## INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents U.S. Patent and Trademark Office Randolph Building, Mail Stop Amendments 401 Dulany Street Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

- [X] 1. This IDS should be considered, in accordance with 37 CFR \$1.97, as it is filed:
- [ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- [X] B. before the mailing date of a first office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 CFR §1.114; or

- [ ] C. after (A) and (B) above, but before final rejection or allowance, and Applicant has made the necessary certification (box "i" below) or paid the necessary fee (box "i" below):
  - [ ] i. Counsel certifies that, upon information and belief, each item of information listed herein either was
    - [ ] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
    - [ ] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR \$1.56(c) more than three months prior to the filing of this IDS.
  - [] ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR \$1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.
- [ ] D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant states as follows under 37 CFR §1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein either was
  - [ ] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

[ ] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR \$1.56(c) more than three months prior to the filing of this IDS.

Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR \$1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.

- [X] 2. In accordance with 37 CFR \$1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR \$1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached, except as explained below:
- [ ] A. Document(s) \_\_\_\_\_\_ is/are deemed substantially cumulative to document(s) \_\_\_\_\_\_, and, in accordance with 37 CFR \$1.98(c), a copy of each of the former document(s) is not enclosed.
- [ ] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under  $35\ U.S.C.\ 120:$

(insert serial numbers and filing dates of prior applications)

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449, PTO/SB/08a and/or PTO/SB/08b (or their BN form equivalents) from the files of the prior application(s) or a fresh BN/SB/08A and/or BN/SB/08B listing these documents, and request that they be considered and made of record in accordance with 37 CFR \$1.98(d). Per 37 CFR

§1.98(d), copies of these documents need not be filed in this application.

- [X] 3. Documents AA-AD, AG, AI, AK and AM are not in the English language. In accordance with 37 CFR \$1.98(a)(3), Applicant states:
  - [X] An English translation of each document AA-AD,

    AG, AI, AK and AM (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.
  - [ ] For documents \_\_\_\_\_\_, a corresponding English-language patent or published application is included on the accompanying Form BN/SB/08A, with a line drawn in the margin connecting the non-English-language document with its corresponding English-language document.
  - [ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ is found in the attached \_\_\_\_\_ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
  - [ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:
  - [ ] A concise explanation of the relevance of
     document(s) \_\_\_\_\_ can be found on page(s)
     of the specification.
  - [ ] A concise explanation of the relevance of document(s) \_\_\_\_ can be found on the attached sheet.
- [X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [ ] 5. Other information being provided for the examiner's consideration follows:

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

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Substitute t	for form 1449A/PTO			Complete if Known		
				Application Number	Not Assigned	
INFO	RMATION D	ISC	LOSURE	Filing Date	Not Assigned	
STATEMENT BY APPLICANT				First Named Inventor	Hiroshi NAKAJIMA et al	
• • • • • • • • • • • • • • • • • • • •		•		Group Art Unit	Not Assigned	
(use as many sheets as necessary)			ecessary)	Examiner Name	Not Assigned	
Sheet	1	of	2	Attorney Docket Number	NAKAJIMA=7	

		NON PATENT LITERATURE DOCUMENTS / OTHER INFORMATION					
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published					
	AA	Comprehensive Dictionary of Chinese Medicines, page 2750.	Part				
	AB	FURUKAWA H: "On the Alkaloids of Nelumbo nucifera Gaertn. IX., Alkoloids of Loti Embryo. (2). Structure of Neferine, a New Biscoclaurine Alkoloid"Chem. Pharm. Bull., (Tokyo), 13, 39 (1965)	Abs.				
	AC	ITO A: "Lian zi xin-derived Alkoloids and their Sedative action" The 50 <sup>th</sup> Annual Meeting of the Japanese Society of Pharmocognosy, Tokyo, Abstract Papers, 2003, p. 116, 1p-34	Part				
	AD	KAWASHIMA et al: Abstract of the 123 <sup>rd</sup> annual meeting of the Pharmaceutical Society of Japan No. 2, page 146, "Study on anti-osteoporotic action of lotus embryo"					
	AE	KUNITOMO et al: "Alkaloids of Nelumbo Nucifera", Faculty of Pharmaceutical Sciences, Phytochemistry, 1973, Vol. 12, pp. 699 to 701.					
	AF	LINDE et al: "St. John's wort for depression - an overview and meta-analysis of randomized clinical trials," (papers), BMJ, volume 313, 253-258, August 3, 1996					
		NAMBA T: "The Encyclopedia of Wakan-Yaku (Traditional Sino-Japanese Medicines) with Color Pictures," Vol. I, pages 216 to 217.	Part				
		NISHIBE et al: "Alkaloids from Embryo of the Seed of Nelumbo Nucifera," Journal of Natural Products, Vol. 49, No. 3, page 547-548, May-June 1986.	Part				
		NISHIZAKI O: "Kenko Shokuhin Hyakka (Encyclopedia for Natural Aliment), March 25, 2003, Buren Shuppan Kabushiki Kaisha, pages 386 to 388.					
		PROTAIS et al: "Effects of Various Isoquinoline Alkaloids on In Vitro <sup>3</sup> H-Dopamine Uptake by Rat Striatal Synaptosomes, Journal of Natural Products, Vol. 58, No. 10, pp. 1475-1484, October 1995)	_				
		SATO et al: Abstract of the 123 <sup>rd</sup> annual meeting of the Pharmaceutical Society of Japan, No. 2, page 112, Effects of antipyretic "Lian zi xin" on rat body temperature.	Part				

Examiner	Date	
Signature	 Considered	

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO				Complete if Known		
				Application Number	Not Assigned	
INFO	RMATION D	ISC	LOSURE	Filing Date	Not Assigned	
STATEMENT BY APPLICANT				First Named Inventor	Hiroshi NAKAJIMA et al	
•		•		Group Art Unit	Not Assigned	
(use as many sheets as necessary)			ecessary)	Examiner Name	Not Assigned	
Sheet	2	of	2	Attorney Docket Number	NAKAJIMA=7	

	NON PATENT LITERATURE DOCUMENTS / OTHER INFORMATION					
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²			
	AL	TOMITA et al: "On the Alkaloids of Nelumbo nucifera:, Chem. Pharm. Bull., Vol. 13, No. 1, pages 39 to 41				
	AM	WATANABE Y: "Experimental Pharmacological Investigation of Isoquinoline-type Alkaloids on Psychotropic Activity," Suzuken Memorial Foundation, Vol. 9, pages 223 to 226	Part			
	AN	XIONG et al: "Effect of neferine on toxicodynamics of dichlorvos for inhibiting rabbit cholinesterase", Acta Pharmacol Sin 2003 Apr; 24 (4): 332-336				
	AO	YASUKAWA et al: "Inhibitory Effect of Cepharanthine and its Related Compounds on 12-o-Tetradecanoylphorbol-13-Acetate-Induced Inflammation and Inhibition of Tumor Promotion by Cepharanthine in Two-Stage Carcinogenesis in Mice," Nihon Univ. J. Med. 31, 229-234, 1989				
	-					

Examiner Signature	Date Consid	dered
3		

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.